PUBLIC HEALTH SERVICE

NON-EXCLUSIVE PATENT LICENSE AGREEMENT
FOR INTERNAL COMMERCIAL USE

COVER PAGE

For PHS internal use only:

License Number:

License Application Number:

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

Licensee:

Additional Remarks:

Public Benefit(s):

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Licensed Products, Processes, Territory, Field of Use and Termination), Appendix C (Royalties), Appendix D (Shipping Information) and Appendix E (Royalty Payment Options). The Parties to this **Agreement** are:

1) The National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**"); and

2) The person, corporation, or institution identified above and on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as "**Licensee**."

PUBLIC HEALTH SERVICE
NON-EXCLUSIVE PATENT LICENSE AGREEMENT

FOR INTERNAL COMMERCIAL USE

This **Agreement** is entered into between the National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**") through the Office of Technology Transfer, **NIH**, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 U.S.A.; and _____ ("**Licensee**"), a corporation of _____, having an office at _____.

PHS and **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, **PHS** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from **PHS** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by **PHS**.

1.3 The Secretary for Health of **HHS** has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions under 35 U.S.C. §§200-212, the Federal Technology Transfer Act of 1986, 15 U.S.C. §3710a, and the regulations governing the licensing of Government-owned inventions, 37 CFR Part 404.

1.4 **PHS** desires to transfer these inventions to the private sector through commercial research licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 **Licensee** desires to acquire the rights to use certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.1 "**Government**" means the government of the United States of America.

2.2 "**Licensed Patent Rights**" shall mean:

(a) U.S. patent applications and patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions claimed in 2.2(a):

(i) continuations-in-part of 2.2(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations; and

(iv) any reissues, reexaminations, and extensions of these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions claimed in 2.2(a): all counterpart foreign applications and patents to 2.2(a) and 2.2(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include 2.2(b) or 2.2(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter of a claim in 2.2(a).

2.3 "**Licensed Products**" means tangible materials, identified in Appendix B, which, in the course of manufacture, use, sale, or importation would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.4 "**Licensed Processes**" means processes, identified in Appendix B, which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.5 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.6 "**Licensed Fields of Use**" means the field of use identified in Appendix B.

3. GRANT OF RIGHTS

3.1 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and to use, but not to sell the **Licensed Products** and **Licensed Processes** in the **Licensed Fields of Use** only.

3.2 **Licensee** has no right to sublicense.

3.3 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than the **Licensed Patent Rights** regardless of whether such patents are dominant or subordinate to the **Licensed Patent Rights**.

3.4 **PHS** acknowledges that information relating to the **Licensed Patent Rights** may be of assistance to **Licensee** in its commercialization efforts. Accordingly, **PHS** shall consider reasonable requests by **Licensee** for access to the inventors of the **Licensed Patent Rights**.

4. ROYALTIES

4.1 **Licensee** agrees to pay **PHS** a non-creditable, nonrefundable license issue royalty as set forth in Appendix C.

4.2 **Licensee** agrees to pay **PHS** a nonrefundable annual royalty as set forth in Appendix C.

4.3 All royalties due under this **Agreement** shall be paid in U.S. dollars, net of all non-U.S. taxes, and payment options are listed in Appendix E. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due.

4.4 Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

5. PERFORMANCE

5.1 Upon receipt and verification of the royalties due under Paragraphs 4.1 and 4.2, **PHS** agrees, if **Licensed Products** are available to **PHS**, to provide **Licensee** with samples of the **Licensed Products** to the individual and address listed in Appendix D and, at reasonable cost to **Licensee**, to replace them in the event of their unintentional destruction. **Licensee** agrees to retain control over the **Licensed Products** and shall not distribute or release them to others without the prior written consent of **PHS**.

5.2 **Licensee** shall expend reasonable efforts and resources to carry out the research development plan submitted with **Licensee's** application for a license and shall begin research within six (6) months of the effective date of this **Agreement**.

5.3 **Licensee** agrees in its use of any **Licensed Products** provided by **PHS** to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines. **Licensee** agrees not to use the **Licensed Products** for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of this research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of this research or trials.

5.4 **Licensee** shall provide written annual reports within sixty (60) days of the end of each calendar year detailing the current status of on-going research using **Licensed Products**.

5.5 All plans and reports required by this Article 5 shall be treated by **PHS** as commercial and financial information obtained from a person and as privileged and confidential and, to the extent permitted under the research development plan by law, not subject to disclosure under the Freedom of Information Act, 5 U.S.C. §552.

6. NEGATION OF WARRANTIES AND INDEMNIFICATION

6.1 **PHS** offers no warranties other than those expressly specified in Article 1.

6.2 **PHS** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

6.3 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR OF ANY **LICENSED PRODUCTS** PROVIDED TO **LICENSEE** UNDER PARAGRAPH 5.1.

6.4 **PHS** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

6.5 **Licensee** shall indemnify and hold **PHS**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by **Licensee**, its directors, employees, or third parties of any **Licensed Patent Rights**, or

(b) the design, manufacture, distribution, or use of any **Licensed Products** or materials provided under Paragraph 5.1, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

6.6 **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

7. TERM, TERMINATION AND MODIFICATION OF RIGHTS

7.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 8.8 are not fulfilled, and shall terminate at the time specified in Appendix B, unless previously terminated under the terms of this Article 7.

7.2 In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 7.3 and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, **PHS** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

7.3 **PHS** shall specifically have the right to terminate this **Agreement** by written notice if **Licensee**:

(a) has not demonstrated that it is executing the research plan submitted with its application for a license or that it has not taken or cannot be expected to take, within a reasonable time, effective steps to achieve the practical application of the **Licensed Patent Rights** as contemplated by this **Agreement**; or

(b) has willfully made a false statement of or willfully omitted a material fact in its application for a license or in any report required by this **Agreement**.

7.4 **PHS** reserves the right according to 35 U.S.C. §209(d)(3) to terminate this **Agreement** if it is determined that this action is necessary to meet the requirements for public use specified by Federal regulations issued after the date of the license and these requirements are not reasonably satisfied by **Licensee**.

7.5 **Licensee** shall have a unilateral right to terminate this **Agreement** by giving **PHS** sixty (60) days written notice to that effect.

7.6 Within thirty (30) days of receipt of written notice of **PHS'** unilateral decision to terminate this **Agreement**, **Licensee** may, consistent with the provisions of 37 CFR §404.11, appeal the decision by written submission to the Director of **NIH** or designee. The decision of the **NIH** Director or designee shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

7.7 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

7.8 Within thirty (30) days of the termination of this **Agreement** under this Article 7 or expiration under Paragraph 7.1, **Licensee** shall submit payment of any royalties due and shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to **PHS** or provide **PHS** with certification of their destruction.

7.9 Paragraphs 4.3, 5.5, 6.1-6.5, 7.6, and 7.8 of this **Agreement** shall survive termination of this **Agreement**.

8. GENERAL PROVISIONS

8.1 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

8.2 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

8.3 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

8.4 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by such other party, and shall be effective as of the date of the postmark of such notice.

8.5 This **Agreement** shall not be assigned by **Licensee** except:

(a) with the prior written consent of **PHS**; or

(b) as part of a sale or transfer of substantially the entire business of **Licensee** relating to operations which concern this **Agreement**; and

(c) **Licensee** shall notify **PHS** within ten (10) days of any assignment of this **Agreement** by **Licensee**.

8.6 **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological materials and other commodities. The transfer of these items may require a license from the appropriate agency of the **Government** or written assurances by **Licensee** that it shall not export other items to certain foreign countries without prior approval of the agency. **PHS** neither represents that a license is or is not required or that, if required, it shall be issued.

8.7 The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modification or termination decisions provided for in Article 7. **Licensee** agrees first to appeal any such unsettled claims or controversies to the designated **PHS** official or designee, whose decision shall be considered the final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.

8.8 The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

PHS NON-EXCLUSIVE PATENT LICENSE AGREEMENT
FOR INTERNAL COMMERCIAL USE

FOR **PHS**:

by: _____ _____
Steven M. Ferguson Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address for **Agreement** notices:

Chief, Monitoring & Enforcement Branch
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

FOR **Licensee** (Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):

Licensee

by: _____ _____
Signature of Authorized Official Date

_____
Printed Name

_____
Title

I. Official and Mailing Address for **Agreement** notices:

_____

_____

_____

_____

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

_____
Name

_____
Title

Mailing Address:

_____

_____

_____

_____

Email Address: _____

Phone: _____

Fax: _____

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

I.

II.

III.

APPENDIX B – LICENSED PRODUCTS, PROCESSES, TERRITORY, FIELD OF USE AND TERMINATION

I. **Licensed Products**:

(a)

II. **Licensed Processes**:

(a)

III. **Licensed Territory**:

(a)

IV. **Licensed Fields of Use**:

(a)

V. Termination:

(a) This **Agreement** shall terminate _____ (X) years from the effective date as defined in Paragraph 7.1.

APPENDIX C – ROYALTIES

Royalties:

I. **Licensee** agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty in the amount of _____ dollars ($X) within thirty (30) days from the effective date of this **Agreement**.

II. **Licensee** agrees to pay to **PHS** a nonrefundable annual royalty in the amount of _____ dollars ($X) as follows:

(a) The first annual royalty is due within thirty (30) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and

(a) Subsequent annual royalty payments are due and payable on January 1 of each calendar year.

APPENDIX D – SHIPPING INFORMATION

Licensee's Shipping Contact: information or questions regarding shipping should be directed to Licensee's Shipping Contact at:

_____ _____

Shipping Contact's Name Title

Phone: () _____ Fax: () _____ E-mail: _____

Shipping Address: Name & Address to which Materials should be shipped (please be specific):

_____

Company Name & Department

Address:

_____

_____

_____

_____

APPENDIX E – ROYALTY PAYMENT OPTIONS

NIH/PHS License Agreements

****In order to process payment via Electronic Funds Transfer sender MUST supply the following information:***

Procedure for Transfer of Electronic Funds to NIH for Royalty Payments

Bank Name: Federal Reserve Bank

ABA# 021030004
TREAS NYC
BNF=/AC-75080031
OBI=Licensee Name and OTT Reference Number
Dollar Amount Wired=$$

NOTE: Only U.S. banks can wire directly to the Federal Reserve Bank. Foreign banks cannot wire directly to the Federal Reserve Bank, but must go through an intermediary U.S. bank. Foreign banks may send the wire transfer to the U.S. bank of their choice, who, in turn forwards the wire transfer to the Federal Reserve Bank.

Mailing Address for Royalty Payments:

National Institutes of Health
P.O. Box 360120
Pittsburgh, PA 15251-6120 USA

Overnight Mail for Royalty Payments only

National Institutes of Health
360120
Mellon Client Service Center
Room 670
500 Ross Street
Pittsburgh, PA 15262-0001

(412) 234-4381 (Customer Service)

Please make checks payable to: *NIH/Patent Licensing*

*The OTT Reference Number **MUST** appear on checks, reports and correspondence*